<u>intensivists</u> and the decision support algorithms of claims 22 and 26 have been made <u>inclusive</u> instead of using Markush practice. No new matter has been added.

Oath/Declaration

The supplemental declaration was objected to as having an incorrect filing date in the body thereof. A corrected supplemental declaration is submitted herewith.

Rejections under 35 USC 102 - Public Use

Claims 15-27 were rejected for public use as being anticipated by multiple references, but primarily relying on the <u>Rosenfeld et al.</u> article. However, to anticipate a claim, the reference must teach every element of the claim:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

In the present case, the alleged public use at John Hopkins University Hospital described by the Rosenfeld et al. article in *Critical Care Medicine* (hereinafter, the Rosenfeld Study) lacks at least the following claim limitations:

In claim 15:

- "a plurality of **geographically dispersed** ICU's" since the Rosenfeld Study disclosed a single 10-bed ICU;
- "a single remote command center for managing healthcare at said plurality of ICU's" since the Rosenfeld Study disclosed alternate monitoring from a plurality of physician homes that contained telemedicine equipment for monitoring the single 10-bed ICU; and

"a computerized patient care management system for monitoring and treating individual
patients at any of said plurality of geographically dispersed ICU's " since the
Rosenfeld Study merely disclosed computer-based videoconferencing and data
transmission equipment at the physician homes for monitoring a single 10-bed ICU.

In claim17:

"a data server/data warehouse for storing and analyzing data from the remote
command center" since the Rosenfeld Study disclosed only physician review of stored
physiologic data, which does nothing to improve future treatment as does the analysis of
remote command center data (i.e., not just patient data, but clinical treatments and
outcomes, etc.).

In claim19:

"each geographically dispersed ICU further comprises a nurses' station electronically
connected to said monitoring equipment and to the remote command center over the at
least one network" since the Rosenfeld Study discloses only twice-a-day discussions with
the nurses.

In claim 21:

"a relational database storing a plurality of decision support algorithms for
intensivists and means for prompting intensivists to provide care to patients based upon
the any of the decision support algorithms" since the Rosenfeld Study discloses only the
videoconferencing of ordinary bedside monitors.

In claim 22:

"decision support algorithms include algorithms for treating: Acalculous Cholecystitis, Acute Pancreatitis Algorithm, Acute Renal Failure-Diagnosis, Acute Renal Failure-Management & Treatment, Adrenal Insufficiency, Agitation and Anxiety, Depression & Withdrawal, Aminoglycoside Dosing and Therapeutic Montoring, an Amphotericin-B Treatment Guidelines, Analgesia, Antibiotic Classification & Costs, Antibiograms Algorithm, Antibiotic associated Colitis Algorithm, ARDS: Hemodynamic Management, ARDS: Steroid Use, ARDS: Ventilator Strategies, Asthma, Bleeding Patient, Bloodstream Infections, Blunt Cardiac Injury, Bradyarrhythmias, Brain Death, Bronchodilator Use in Ventilator Patients, Bronchoscopy & Thoracentesis Guidelines,

November 7, 2002 12 Atty. Dckt. 2484-001

Candiduria, Cardiogenic Shock, CardioPulmonary Resuscitation Guideline, Catheter Related Septicemia, a Catheter Replacement Strategies, Cervical Cord Injury, Congestive Heart Failure, Copd Exacerbation & Treatment, CXR (Indications), Dealing with Difficult patients and families, Diabetic Ketoacidosis, Dialysis, Diurectic Use, Drug Changes with Renal Dysfunction, Emergency Cardiac Pacing, Endocarditis Diagnosis and Treatment, Endocarditis Prophylaxis, End of Life Decisions, Endotracheal Tubes & Tracheotomy, Ethical Guidelines, Febrile Neutropenia, FUO, Fluid Resusditation, Guillain-Barre Syndrome, Heparin, Heparin-Induced Thrombocytopenia, Hepatic Encephalopathy, Hepatic Failure, HIV + Patent Infections, Hypercalcemia Diagnosis and Treatment, Hypercalcemia Insulin Treatment, Hyperkalemia: Etiology & Treatment, Hypernatremia: Etiology & Treatment, Hypertensive Crisis, Hypokalemia: Etiology & Treatment, Hyponatremia: Etiology & Treatment, Hypothermia, Identification of Cervical Cord Injury, Implantable Cardio-defibrillator, Intra-Aortic Balloon Device, Intracerebral Hemorrhage, Latex Allergy, Magnesium Administration, Management of Hypotension, Inotropes, Management of Patients with Ascites, Empiric Meningitis, Meningitis, a Myasthenia Gravis, Myocardial Infarction, Myocardial Infarction with left bundle branch block, Necrotizing Soft Tissue Infections, Neuromuscular Blockers, Neuromuscular Compleations of Critical Illness, Non-Infectious Causes of Fever, Non-Traumatic Coma, Noninvasive Modes of Ventilation, Nutritional Management, Obstertrical Complication, Oliguria, Oliguria, Open Fractures, Open Fractures, Ophthalmic Infections, Organ Procurement Guidelines, PA Catheter Guideline and Troubleshooting, Pancreatitis, Penetrating Abdominal Injury, Penetrating Chest Injury, Penicillin Allergy, Penicillin Allergy, Permanent Pacemaker and Indications, Pneumonia Community Acquired, Pneumonia Hospital Acquired, Post-Op Bleeding, Post-Op Hypertension, Post-Op Hypertension, Post-Op Management of Abdominal, Post-Op Management of Carotid, Post-Op Management of Open Heart, Post-Op Management of Thoracotomy, Post-Op Myocardial Ischemia (Non-Cardiac Arrhythmias after Cardiac Surgery), Post-Op Power Weaning, Pressure Ulcers, Pulmonary Embolism Diagnosis, Pulmonary Embolism Treatment, Respiratory Isolation, Sedation, Seizure, Status Epilepticus, Stroke, Sub-Arachnoid Hemorrhage, Supra-Ventricular Tachyarrythmia, Supra-Ventricular Tachycardia, Wide Complex

QRS Tachycardia, Therapeutic Drug Montoring, Thrombocytopenia, Thrombolytic Therapy, Transfusion Guidelines, Traumatic Brain Injury, Assessment of Sedation, Sedation, Septic Shock, Bolus Sliding Scale Midazolam, Short Term Sedation Process, Sinusitis, SIRS, Spinal Cord Injury, Steroid Replacement Strategy, Thyroid Disease, Transplant Infection Prophylaxis, Transplant Related Infections, Treatment of Airway Obstruction, Unknown Poisoning, Unstable Angina, Upper GI Bleeding Stress Prophylaxis, Vancomycin, Upper GI Bleeding Non-Variceal, Upper GI Bleeding Variceal, Use of Hematopoetic Growth Factors, Ventialtor Weaning, Ventialtor Weaning Protocol, Venous Thrombosis Diagnostic and Treatment, Venous Thromboembolism Phrophylaxis, Ventricular Arrythmia, Warfarin, Warfarin Dosing, and Wound Healing Strategies" since the Rosenfeld Study fails to disclose any decision support algorithms.

In claim 23:

 "order writing software means for providing knowledge-based recommendations and prescriptions for medication based upon the clinical data" since the Rosenfeld Study disclosed nothing of this sort.

In claim 24:

• "knowledge-based vital sign/hemodynamic algorithms that prompt said intensivist to engage in early intervention" since the Rosenfeld Study disclosed only ordinary bedside monitors (i.e., not knowledge-based vital sign/hemodynamic algorithms).

In claim 25:

- "monitoring patients in a plurality of geographically dispersed ICU's" since the Rosenfeld Study disclosed only a single 10-bed ICU;
- "communicating the information from the patient monitoring to a single remote
 command center" since the Rosenfeld Study disclosed alternate monitoring from a
 plurality of physician homes that contained telemedicine equipment for monitoring the
 single 10-bed ICU; and
- "an intensivist reviewing decision support algorithms for intensivists that provide
 guidance for treating a plurality of critical care conditions" since the Rosenfeld Study
 disclosed only the videoconferencing of ordinary bedside monitors.

In claim 26:

"decision support algorithms include algorithms for treating: Acalculous Cholecystitis, Acute Pancreatitis Algorithm, Acute Renal Failure-Diagnosis, Acute Renal Failure-Management & Treatment, Adrenal Insufficiency, Agitation and Anxiety, Depression & Withdrawal, Aminoglycoside Dosing and Therapeutic Montoring, an Amphotericin-B Treatment Guidelines, Analgesia, Antibiotic Classification & Costs, Antibiograms Algorithm, Antibiotic associated Colitis Algorithm, ARDS: Hemodynamic Management, ARDS: Steroid Use, ARDS: Ventilator Strategies, Asthma, Bleeding Patient, Bloodstream Infections, Blunt Cardiac Injury, Bradyarrhythmias, Brain Death, Bronchodilator Use in Ventilator Patients, Bronchoscopy & Thoracentesis Guidelines, Candiduria, Cardiogenic Shock, CardioPulmonary Resuscitation Guideline, Catheter Related Septicemia, a Catheter Replacement Strategies, Cervical Cord Injury, Congestive Heart Failure, Copd Exacerbation & Treatment, CXR (Indications), Dealing with Difficult patients and families, Diabetic Ketoacidosis, Dialysis, Diurectic Use, Drug Changes with Renal Dysfunction, Emergency Cardiac Pacing, Endocarditis Diagnosis and Treatment, Endocarditis Prophylaxis, End of Life Decisions, Endotracheal Tubes & Tracheotomy, Ethical Guidelines, Febrile Neutropenia, FUO, Fluid Resusditation, Guillain-Barre Syndrome, Heparin, Heparin-Induced Thrombocytopenia, Hepatic Encephalopathy, Hepatic Failure, HIV + Patent Infections, Hypercalcemia Diagnosis and Treatment, Hypercalcemia Insulin Treatment, Hyperkalemia: Etiology & Treatment, Hypernatremia: Etiology & Treatment, Hypertensive Crisis, Hypokalemia: Etiology & Treatment, Hyponatremia: Etiology & Treatment, Hypothermia, Identification of Cervical Cord Injury, Implantable Cardio-defibrillator, Intra-Aortic Balloon Device, Intracerebral Hemorrhage, Latex Allergy, Magnesium Administration, Management of Hypotension, Inotropes, Management of Patients with Ascites, Empiric Meningitis, Meningitis, a Myasthenia Gravis, Myocardial Infarction, Myocardial Infarction with left bundle branch block, Necrotizing Soft Tissue Infections, Neuromuscular Blockers, Neuromuscular Compleations of Critical Illness, Non-Infectious Causes of Fever, Non-Traumatic Coma, Noninvasive Modes of Ventilation, Nutritional Management, Obstertrical Complication, Oliguria, Oliguria, Open Fractures, Open Fractures, Ophthalmic Infections, Organ Procurement Guidelines, PA Catheter

Guideline and Troubleshooting, Pancreatitis, Penetrating Abdominal Injury, Penetrating Chest Injury, Penicillin Allergy, Penicillin Allergy, Permanent Pacemaker and Indications, Pneumonia Community Acquired, Pneumonia Hospital Acquired, Post-Op Bleeding, Post-Op Hypertension, Post-Op Hypertension, Post-Op Management of Abdominal, Post-Op Management of Carotid, Post-Op Management of Open Heart, Post-Op Management of Thoracotomy, Post-Op Myocardial Ischemia (Non-Cardiac Arrhythmias after Cardiac Surgery), Post-Op Power Weaning, Pressure Ulcers, Pulmonary Embolism Diagnosis, Pulmonary Embolism Treatment, Respiratory Isolation, Sedation, Seizure, Status Epilepticus, Stroke, Sub-Arachnoid Hemorrhage, Supra-Ventricular Tachyarrythmia, Supra-Ventricular Tachycardia, Wide Complex QRS Tachycardia, Therapeutic Drug Montoring, Thrombocytopenia, Thrombolytic Therapy, Transfusion Guidelines, Traumatic Brain Injury, Assessment of Sedation, Sedation, Septic Shock, Bolus Sliding Scale Midazolam, Short Term Sedation Process, Sinusitis, SIRS, Spinal Cord Injury, Steroid Replacement Strategy, Thyroid Disease, Transplant Infection Prophylaxis, Transplant Related Infections, Treatment of Airway Obstruction, Unknown Poisoning, Unstable Angina, Upper GI Bleeding Stress Prophylaxis, Vancomycin, Upper GI Bleeding Non-Variceal, Upper GI Bleeding Variceal, Use of Hematopoetic Growth Factors, Ventilator Weaning, Ventilator Weaning Protocol, Venous Thrombosis Diagnostic and Treatment, Venous Thromboembolism Phrophylaxis, Ventricular Arrythmia, Warfarin, Warfarin Dosing, and Wound Healing Strategies" since the Rosenfeld Study failed to disclose any such algorithms.

In claim 27:

 "a data server/ data warehouse storing and analyzing patient data from the command center and providing analysis of results over a second network to the command center" since the Rosenfeld Study disclosed only physician review of stored physiological data. Indeed, the Rosenfeld Study was not a public use of the presently claimed invention, but only a feasibility study into the concept of extending the availability of intensivists via telemedicine.

The present inventors extended on the basic concept of the Rosenfeld Study by inventing the additional means and steps necessary to make the concept economically viable - a patient care management system to allow a single remote command center to monitor a plurality of ICU's on a 24/7 basis by using a computerized patient care management system. An additional benefit of the single remote command center monitoring a plurality of ICU's is the ability to provide consistent care to geographically dispersed ICU's. Consistent care is improved by using decision support algorithms of the computerized patient care management system. The collected data can be stored and analyzed to improve the decision support algorithms.

As additional support for Applicants' assertion that the Rosenfeld Study was not a public use of the presently claimed invention, Applicants submit affidavits from Drs. Michael Berman, Jeffrey Schwartz, Eugene Burke, Mervyn Maze, Steven Corwin, and Rodney Hochman, who are all knowledgeable of the Rosenfeld Study and skilled in the art of Intensive Care Medicine as trained intensivists and/or Intensive Care administrators.

Each of these Intensive Care specialists has signed an affidavit attesting to their belief that the claimed invention is materially different from the Rosenfeld Study for multiple reasons.

They agree that the claimed invention provides centralized monitoring of a plurality of geographically disparate ICU's, whereas the Rosenfeld Study monitored only one single specialty 10-bed ICU.

They agree that the capability of the claimed invention to allow a physician-led team, made up of intensive care specialists, critical care nurses, and clerical support personnel (care

team), to care for patients in multiple ICU's in disparate geographic locations, either within a building or in different buildings, simultaneously that creates new efficiencies and offers the potential to change the care paradigm for ICU patients. Thus, the expertise of the care team is leveraged over many ICU patients, who could not otherwise (without claimed intervention) be cared for by a single team.

They further agree that, in contrast to the Rosenfeld Study where a single intensivist monitored faxed information, or initiated communication to view a single patient's bedside monitor over a personal computer, the claimed invention uses a computerized patient care management system that feeds key clinical information on multiple ICU patients simultaneously to the remote monitoring care team. The claimed invention includes imbedded decision support algorithms that further assist the care team in the continuous monitoring of large numbers of ICU patients. The claimed invention analyzes simultaneously all incoming patient physiologic data (from the bedside monitors) and laboratory data and provides visual alarms for the care team that alert them to detrimental trends in patient vital signs and/or laboratory values that they might not otherwise be aware of. They agree that these features of the claimed invention allow a single physician-led team to care for patients in multiple, geographically disparate sites simultaneously. These features are totally lacking from the Rosenfeld Study and are not suggested by the study in any way.

They also agree that the claimed invention provides for 24-hour dedicated monitoring/management by a care team. The care team provides this service from a dedicated monitoring facility comprising equipment and decision support algorithms developed explicitly for this purpose. The claimed invention provides for automated warnings relating to vital signs and trends in vital signs, provides assessment of those trends for the intensivist, and makes

November 7, 2002 18 Atty. Dckt. 2484-001

recommendations for intervention available for consideration by the intensivist. The care team has no other care responsibilities during the time it is monitoring/managing the multiple geographically disparate ICU(s). The attention of the care team is devoted to the ICU patients and only the ICU patients.

And they further agree that, in contrast to the present invention, the Rosenfeld Study provided only 4-5 hours of ad hoc monitoring by a single intensivist from the intensivist's home (i.e. no continuous monitoring, no support personnel, and no dedicated facility). Further, the intensivist monitoring was not triggered in any automated way by any form of decision support algorithms, but was conducted periodically by the intensivist, as he deemed fit and time permitted. The intensivist in the Rosenfeld Study was solely responsible for analyzing the data, deducing trends in the patent's vital signs, assessing the meaning of the trends, and deciding on the corrective action to be taken – without access to any software tools to assist in these tasks. The software tools in the claimed invention create efficiencies that enable a single, intensivist-led team to monitor and care for large number of ICU patients.

Each of the aforementioned Intensive Care specialists believe that remote, 24-hour intensivist-lead care team monitoring of ICU patients in multiple geographically disparate locations is not taught by the Rosenfeld Study, nor would one of skill in the art make the required changes to the equipment and procedures of the Rosenfeld Study to arrive at the present invention, as further discussed in each of their respective affidavits.

For the reasons stated above, Applicants submit that claims 15, 17-19 and 21-27 are not anticipated under the public use clause of 35 USC 102(b) in view of the public use described by Rosenfeld Study since the Rosenfeld Study fails to teach or suggest the presently claimed invention.

November 7, 2002 19 Atty. Dckt. 2484-001

Claim Rejections - 35 USC 103

The final rejection of July 19, 2002 did not specifically address claim rejections under 35 USC 103. However, since these bases of rejection were discussed at the personal interview and in a subsequent teleconference, they will be addressed herein so that the Examiner can be assured that Applicants are cognizant of this potential concern.

Claims 21-22, 24 and 26-27 (formerly 7-8, 10 and 12-13) were rejected under 35 USC 103 as being obvious over the Rosenfeld Study in view of <u>Levin et al.</u> or <u>Benigno et al.</u>

The basic premise of the rejection is that the Rosenfeld Study disclosed everything except decision support algorithms, which are taught by <u>Levin et al.</u> or <u>Benigno et al.</u> As an initial matter, Applicants note that decision support algorithms are further included in claim 25.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (See M.P.E.P. Section 2143).

No Motivation to Combine

In the present case, none of these criteria have been met by the references cited in the Office Action. First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the Rosenfeld Study or combine it with <u>Levin et al.</u> or <u>Benigno et al.</u> The present invention provides decision support algorithms for the intensivists.

The Rosenfeld Study relies on the expertise of the intensivists to provide decision support to the ICU staff such that there would be no reason to suggest an additional decision support mechanism for the intensivists. This reflects on the prior art monitoring paradigm, wherein the lowest skill staff (nurses) monitor the patients and use higher skilled physicians or algorithms for decision support.

This same prior art monitoring paradigm is reflected in Levin et al., which provides primary care physicians with decision support from remote algorithms and higher skilled specialists. Again, the algorithms are meant for the lower skill level (primary care physician) not the specialist (cardiologist).

Benigno et al. fails to discuss the party for which the algorithms are designed to inform, but does nothing to reverse the monitoring paradigm of the prior art or suggest that experts, such as intensivists, should use decision support algorithms.

As additional support for Applicants' assertion that the prior art fails to suggest modification of the Rosenfeld Study to obtain the presently claimed invention, Applicants again submit affidavits from Drs. Michael Berman, Jeffrey Schwartz, Eugene Burke, Mervyn Maze, Steven Corwin, and Rodney Hochman, who are both knowledgeable of the Rosenfeld Study and representative of those skilled in the art of Intensive Care Medicine.

Each of these Intensive Care specialists signed statements attesting to their belief that remote, 24-hour intensivist-lead care team monitoring of ICU patients in multiple geographically disparate locations is not taught by the Rosenfeld Study nor would one of skill in the art make the required changes to the equipment and procedures of the Rosenfeld Study to arrive at the present invention and cited multiple reasons for this belief.

Among the reasons, the Intensive Care specialists cited their belief that the generally accepted medical monitoring paradigm in ICU's with intensivists on-staff is for the intensivists to conduct rounds with the staff, and for ICU nurses and other physicians to notify the intensivists of emergencies on an as-needed basis. The Rosenfeld Study subscribed to this generally accepted model of intensivist deployment in ICU's, daily rounds, periodic monitoring, and responding to requests for assistance from on-site personnel.

They further cited their belief that the monitoring paradigm presently employed by hospitals is to provide most continuous direct monitoring of patients by lower-skilled bedside nurses. These personnel, with only bedside patient monitoring equipment and visual inspection, are relied on to make the decision to contact specialists, such as intensivists, for ICU patients.

The Intensive Care specialist also agree that at the time the clinical study, it was unprecedented to have an intensivist functioning in a dedicated monitoring capacity and NOT attending to other functions and that the Rosenfeld study was not the same model as that used in the present invention's model. The functioning of the current system constitutes an entirely different manner of monitoring multiple, geographically disparate ICU's than the clinical study which monitored but a single ICU without the analytical support offered in the present invention system.

With respect to decision support algorithms, the Intensive Care specialists signed affidavits attesting to their belief that providing either a computerized patient care management system or a set of decision support algorithms to a remote care team (or a combination thereof) is not taught by the Rosenfeld Study, and neither the paper nor the standard practices of the time would suggest such a modification for multiple reasons.

Among the reasons cited, the Intensive Care specialists cited their belief that the use of computerized patient care management systems at the time of the invention was limited in major hospitals to the recording of patient data to be reviewed by a physician later in time, and those isolated systems that sound an alarm when an extreme condition in a patient's vital signs is reached (i.e. cardiac arrest). Further, computerized decision support algorithms in the medical community were not available.

Additionally, the Intensive Care specialists cited their belief that when computerized patient care management systems are deployed by hospitals, they are provided at the bedside or ICU nursing stations. They are not provided remotely to a physician. Instead, physicians are contacted by a bedside nurse (via a "pager") to inform them that a problem has developed.

The Intensive Care specialists agree that since the accepted wisdom of the medical community is to deploy patient care management systems and/or paper-based decision support for lower-skilled medical care givers on-site, there would be no reason to deploy these systems at a remote site for a care giver having the higher-skills of an intensivist.

No Reasonable Expectation of Success

Even if one where to modify the Rosenfeld Study to include decision support algorithms of <u>Levin et al.</u> or <u>Benigno et al.</u>, there is no reasonable expectation that the algorithms would be inclusive of all of those presented in claims 22 and 26.

All Claim Limitations Not Shown

As noted above with respect to 35 USC 102, the Rosenfeld Study did NOT disclose everything except decision support algorithms, and neither <u>Levin et al.</u> nor <u>Benigno et al.</u> provides for (i.e., discloses or teaches) the missing claim limitations cited above.

November 7, 2002 23 Atty. Dckt. 2484-001

In view of the above arguments, Applicant respectfully submits that claims 15, 17-19 and 21-27 are novel and non-obvious over the cited prior art.

Conclusion

As stated in the attached affidavits and repeated herein, the primary cited prior art, the Rosenfeld Study, evaluated the potential of "currently available technology" to "extend the effective reach of intensivists," but failed to disclose or suggest any of the additional technology of the presently claimed invention, such as (i) intensivist access to patient care management systems and/or decision support algorithms, that are required to effectively scale the monitoring to a greater number of patients and (ii) central command center monitoring that is required to effect a viable remote ICU monitoring model, (iii) monitoring of a plurality of geographically disparate healthcare locations/ICUs from a single remote command center, (iv) the use of a care team to enable monitoring and intervention on multiple patients in geographically different locations and (v) a data server/data warehouse for storing and analyzing data.

For the reasons cited above, Applicants submit that claims 15,17-19 and 21-27 are in condition for allowance and requests reconsideration of the application. If there remain any issues that may be disposed of via a telephonic interview, the Examiner is kindly invited to contact the undersigned at the local exchange given below.

Respectfully submitted,

ROBERTS ABOKHAIR & MARDULA, LLC

Jon Roberts, Esq.

Registration No.: 31,293

(703) 391-2900

MARKED-UP VERSION SHOWING CHANGES MADE

In the claims:

The claims were amended as follows:

15. (Amended) A system for providing continuous, expert network health care services from a remote location comprising:

a plurality of geographically dispersed ICU's [health care locations];

[at least one] a single remote command center for managing healthcare at said plurality of ICU's [health care locations]; and

at least one network;

wherein said plurality of <u>ICU's</u> [health care locations] are electronically connected to said [at least one] remote command center by the <u>at least one</u> network, and

wherein said [at least one] remote command center [provides] <u>further comprises a computerized patient care management system for monitoring and treating individual patients at any of said plurality of geographically dispersed ICU's for intensivist monitoring of the plurality of <u>ICU's</u> [health care locations] 24 hours per day, seven days per week.</u>

16. Cancelled.

- 17. (Amended) The system for providing continuous, expert network health care services from a remote location of claim [16] 15 wherein said computerized patient care management system further comprises a data server/data warehouse for storing and analyzing data from the [at least one] remote command center.
- 18. (New) The system for providing continuous, expert network health care services from a remote location of claim 15 wherein each of the plurality of geographically dispersed ICU's [health care locations] further comprises patient monitoring equipment electronically connected to the [at least one] remote command center over the network.
- 19. (Amended) The system for providing continuous, expert network health care services from a remote location of claim 18 wherein each geographically dispersed ICU [health care

location] further comprises a nurses' station electronically connected to said monitoring equipment and to the [at least one] remote command center over the at least one network.

20. Cancelled.

22.

- 21. (Amended) The system for providing continuous, expert network health care services from a remote location of claim [16] 15 wherein said computerized patient care management system further comprises a relational database [for] storing a plurality of decision support algorithms for intensivists and means for prompting intensivists to provide care to patients based upon the any of the decision support algorithms.
- (Amended) The system for providing continuous, expert network health care services from a remote location of claim 21 wherein said decision support algorithms [are selected from the group consisting of include algorithms for treating: Acalculous Cholecystitis, Acute Pancreatitis Algorithm, Acute Renal Failure-Diagnosis, Acute Renal Failure-Management & Treatment, Adrenal Insufficiency, Agitation and Anxiety, Depression & Withdrawal, Aminoglycoside Dosing and Therapeutic Montoring, an Amphotericin-B Treatment Guidelines, Analgesia, Antibiotic Classification & Costs, Antibiograms Algorithm, Antibiotic associated Colitis Algorithm, ARDS: Hemodynamic Management, ARDS: Steroid Use, ARDS: Ventilator Strategies, Asthma, Bleeding Patient, Bloodstream Infections, Blunt Cardiac Injury, Bradyarrhythmias, Brain Death, Bronchodilator Use in Ventilator Patients, Bronchoscopy & Thoracentesis Guidelines, Candiduria, Cardiogenic Shock, CardioPulmonary Resuscitation Guideline, Catheter Related Septicemia, a Catheter Replacement Strategies, Cervical Cord Injury, Congestive Heart Failure, Copd Exacerbation & Treatment, CXR (Indications), Dealing with Difficult patients and families, Diabetic Ketoacidosis, Dialysis, Diurectic Use, Drug Changes with Renal Dysfunction, Emergency Cardiac Pacing, Endocarditis Diagnosis and Treatment, Endocarditis Prophylaxis, End of Life Decisions, Endotracheal Tubes & Tracheotomy, Ethical Guidelines, Febrile Neutropenia, FUO, Fluid Resusditation, Guillain-Barre Syndrome, Heparin, Heparin-Induced Thrombocytopenia, Hepatic Encephalopathy, Hepatic Failure, HIV + Patent Infections, Hypercalcemia Diagnosis and Treatment, Hypercalcemia Insulin Treatment, Hyperkalemia: Etiology & Treatment,

26 Atty. Dckt. 2484-001 November 7, 2002

Hypernatremia: Etiology & Treatment, Hypertensive Crisis, Hypokalemia: Etiology & Treatment, Hyponatremia: Etiology & Treatment, Hypothermia, Identification of Cervical Cord Injury, Implantable Cardio-defibrillator, Intra-Aortic Balloon Device, Intracerebral Hemorrhage, Latex Allergy, Magnesium Administration, Management of Hypotension, Inotropes, Management of Patients with Ascites, Empiric Meningitis, Meningitis, a Myasthenia Gravis, Myocardial Infarction, Myocardial Infarction with left bundle branch block, Necrotizing Soft Tissue Infections, Neuromuscular Blockers, Neuromuscular Compleations of Critical Illness, Non-Infectious Causes of Fever, Non-Traumatic Coma, Noninvasive Modes of Ventilation, Nutritional Management, Obstertrical Complication, Oliguria, Oliguria, Open Fractures, Open Fractures, Ophthalmic Infections, Organ Procurement Guidelines, PA Catheter Guideline and Troubleshooting, Pancreatitis, Penetrating Abdominal Injury, Penetrating Chest Injury, Penicillin Allergy, Penicillin Allergy, Permanent Pacemaker and Indications, Pneumonia Community Acquired, Pneumonia Hospital Acquired, Post-Op Bleeding, Post-Op Hypertension, Post-Op Hypertension, Post-Op Management of Abdominal, Post-Op Management of Carotid, Post-Op Management of Open Heart, Post-Op Management of Thoracotomy, Post-Op Myocardial Ischemia (Non-Cardiac Arrhythmias after Cardiac Surgery), Post-Op Power Weaning, Pressure Ulcers, Pulmonary Embolism Diagnosis, Pulmonary Embolism Treatment, Respiratory Isolation, Sedation, Seizure, Status Epilepticus, Stroke, Sub-Arachnoid Hemorrhage, Supra-Ventricular Tachyarrythmia, Supra-Ventricular Tachycardia, Wide Complex QRS Tachycardia, Therapeutic Drug Montoring, Thrombocytopenia, Thrombolytic Therapy, Transfusion Guidelines, Traumatic Brain Injury, Assessment of Sedation, Sedation, Septic Shock, Bolus Sliding Scale Midazolam, Short Term Sedation Process, Sinusitis, SIRS, Spinal Cord Injury, Steroid Replacement Strategy, Thyroid Disease, Transplant Infection Prophylaxis, Transplant Related Infections, Treatment of Airway Obstruction, Unknown Poisoning, Unstable Angina, Upper GI Bleeding Stress Prophylaxis, Vancomycin, Upper GI Bleeding Non-Variceal, Upper GI Bleeding Variceal, Use of Hematopoetic Growth Factors, Ventialtor Weaning, Ventialtor Weaning Protocol, Venous Thrombosis Diagnostic and Treatment, Venous Thromboembolism Phrophylaxis, Ventricular Arrythmia, Warfarin, Warfarin Dosing, and Wound Healing Strategies.

27

- 23. (Amended) The system for providing continuous, expert network health care services from a remote location of claim [16] 15 wherein said computerized patient care management system further comprises order writing software means for providing knowledge-based recommendations and prescriptions for medication based upon the clinical data.
- 24. (Amended) The system for providing continuous, expert network health care services from a remote location of claim [16] 15 wherein said computerized patient care management system further comprises knowledge-based vital sign/hemodynamic algorithms that prompt said intensivist to engage in early intervention.
- 25. (Amended) A method for providing continuous expert critical care comprising:

 monitoring patients in a plurality of geographically dispersed ICU's;

 communicating the information from the patient monitoring to [at least one] a single remote command center over a first network

receiving and analyzing the information from the patient monitoring at the <u>remote</u> command center over the first network; and

providing guidance from the <u>remote</u> command center to the plurality of <u>geographically</u> <u>dispersed</u> ICU's to take actions regarding patient care, wherein the providing guidance from the <u>remote</u> command center further comprises an intensivist reviewing decision support algorithms <u>for intensivists</u> that provide guidance for treating a plurality of critical care conditions.

26. (Amended) The method for providing continuous expert critical care of claim 25 wherein the decision support algorithms [are taken from the group consisting of] <u>include</u> algorithms for treating:

Acalculous Cholecystitis, Acute Pancreatitis Algorithm, Acute Renal Failure-Diagnosis, Acute Renal Failure-Management & Treatment, Adrenal Insufficiency, Agitation and Anxiety, Depression & Withdrawal, Aminoglycoside Dosing and Therapeutic Montoring, an Amphotericin-B Treatment Guidelines, Analgesia, Antibiotic Classification & Costs, Antibiograms Algorithm, Antibiotic associated Colitis Algorithm, ARDS: Hemodynamic Management, ARDS: Steroid Use, ARDS: Ventilator Strategies, Asthma, Bleeding Patient, Bloodstream Infections, Blunt Cardiac Injury, Bradyarrhythmias, Brain Death, Bronchodilator

Use in Ventilator Patients, Bronchoscopy & Thoracentesis Guidelines, Candiduria, Cardiogenic Shock, CardioPulmonary Resuscitation Guideline, Catheter Related Septicemia, a Catheter Replacement Strategies, Cervical Cord Injury, Congestive Heart Failure, Copd Exacerbation & Treatment, CXR (Indications), Dealing with Difficult patients and families, Diabetic Ketoacidosis, Dialysis, Diurectic Use, Drug Changes with Renal Dysfunction, Emergency Cardiac Pacing, Endocarditis Diagnosis and Treatment, Endocarditis Prophylaxis, End of Life Decisions, Endotracheal Tubes & Tracheotomy, Ethical Guidelines, Febrile Neutropenia, FUO, Fluid Resusditation, Guillain-Barre Syndrome, Heparin, Heparin-Induced Thrombocytopenia, Hepatic Encephalopathy, Hepatic Failure, HIV + Patent Infections, Hypercalcemia Diagnosis and Treatment, Hypercalcemia Insulin Treatment, Hyperkalemia: Etiology & Treatment, Hypernatremia: Etiology & Treatment, Hypertensive Crisis, Hypokalemia: Etiology & Treatment, Hyponatremia: Etiology & Treatment, Hypothermia, Identification of Cervical Cord Injury, Implantable Cardio-defibrillator, Intra-Aortic Balloon Device, Intracerebral Hemorrhage, Latex Allergy, Magnesium Administration, Management of Hypotension, Inotropes, Management of Patients with Ascites, Empiric Meningitis, Meningitis, a Myasthenia Gravis, Myocardial Infarction, Myocardial Infarction with left bundle branch block, Necrotizing Soft Tissue Infections, Neuromuscular Blockers, Neuromuscular Compleations of Critical Illness, Non-Infectious Causes of Fever, Non-Traumatic Coma, Noninvasive Modes of Ventilation, Nutritional Management, Obstertrical Complication, Oliguria, Oliguria, Open Fractures, Open Fractures, Ophthalmic Infections, Organ Procurement Guidelines, PA Catheter Guideline and Troubleshooting, Pancreatitis, Penetrating Abdominal Injury, Penetrating Chest Injury, Penicillin Allergy, Penicillin Allergy, Permanent Pacemaker and Indications, Pneumonia Community Acquired, Pneumonia Hospital Acquired, Post-Op Bleeding, Post-Op Hypertension, Post-Op Hypertension, Post-Op Management of Abdominal, Post-Op Management of Carotid, Post-Op Management of Open Heart, Post-Op Management of Thoracotomy, Post-Op Myocardial Ischemia (Non-Cardiac Arrhythmias after Cardiac Surgery), Post-Op Power Weaning, Pressure Ulcers, Pulmonary Embolism Diagnosis, Pulmonary Embolism Treatment, Respiratory Isolation, Sedation, Seizure, Status Epilepticus, Stroke, Sub-Arachnoid Hemorrhage, Supra-Ventricular Tachyarrythmia, Supra-Ventricular Tachycardia, Wide Complex QRS Tachycardia, Therapeutic Drug Montoring, Thrombocytopenia, Thrombolytic Therapy, Transfusion Guidelines, Traumatic Brain Injury,

Assessment of Sedation, Sedation, Septic Shock, Bolus Sliding Scale Midazolam, Short Term Sedation Process, Sinusitis, SIRS, Spinal Cord Injury, Steroid Replacement Strategy, Thyroid Disease, Transplant Infection Prophylaxis, Transplant Related Infections, Treatment of Airway Obstruction, Unknown Poisoning, Unstable Angina, Upper GI Bleeding Stress Prophylaxis, Vancomycin, Upper GI Bleeding Non-Variceal, Upper GI Bleeding Variceal, Use of Hematopoetic Growth Factors, Ventilator Weaning, Ventilator Weaning Protocol, Venous Thrombosis Diagnostic and Treatment, Venous Thromboembolism Phrophylaxis, Ventricular Arrythmia, Warfarin, Warfarin Dosing, and Wound Healing Strategies.

27. (Amended) The method for providing continuous expert critical care of claim 25 further comprising a data server/ data warehouse storing and analyzing patient data from the [at least one] command center and providing analysis [in] of results over a second network to the [at least one] command center.